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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,557	04/28/2006	Michael Solomon	20712-506 NATL	2860
30623 7590 01/07/2009 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER CLARK, SARA ELIZABETH	
			ART UNIT 4121	PAPER NUMBER
			MAIL DATE 01/07/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,557	Applicant(s) SOLOMON, MICHAEL	
	Examiner SARA E. CLARK	Art Unit 4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application is a 35 U.S.C. 371 (national stage application) of PCT/US04/18985, filed 06/16/2004, which claims priority to Provisional Application 60/478,764, filed 06/16/2003, and to Provisional Application 60/496,621, filed 08/20/2003.

Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted:

- ✧ Group I, claims 1-10, drawn to a method of using structural formula II, IIIa, or IIIb;
- Group II, claims 11-25, drawn to a method of using structural formula IVa, IVb, Va, Vb, or compound 1.

2. As set forth in Rule 13.1 of the Patent Cooperation Treaty, "the international application shall relate to one invention only or to a group of inventions." In the case of a group of inventions, PCT Rule 13.2 requires Unity of Invention: "where a group of inventions is claimed in one and the same international application, the requirement of unity referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those

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technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.”

3. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I and II are directed to methods of treating a sleep disorder, each using a distinct chemical species containing a distinct moiety such that each chemical species is of a dissimilar nature. Therefore, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and, *a priori*, unity of invention is lacking.

Election of Species

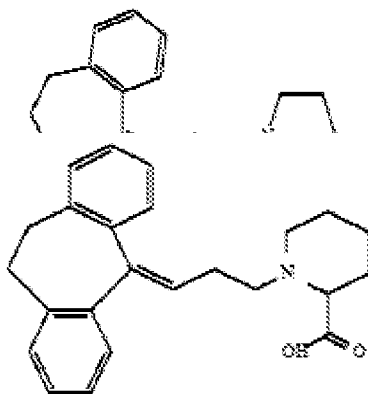
4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. If Applicant elects Group I or II, the following species election is required:

Define one specific compound by specifying each variable R group, linker, and/or heteroatom.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1, because the species lack the same or corresponding technical feature. Specifically, compounds within both Groups I and II are known in the treatment of other conditions. US Pat. 5,874,428, example 14, col. 19 (issued 2/23/1999) teaches

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the use of 1-(3-(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-ylidene)-1-propyl)-2-pyrrolidinecarboxylic acid in the treatment of hyperalgesic and/or inflammatory



conditions. This structure reads on Structure IIIb of claim 6, and therefore anticipates all structures recited in Group I (claims 1-10). US Pat. 5,874,428 also teaches the use of 1-(3-(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-ylidene)-1-propyl)-2-piperidinecarboxylic acid in the treatment of hyperalgesic and/or inflammatory conditions. This structure reads on Structure Vb of claim 16, and therefore anticipates all structures recited in Group II (claims 16-25). Therefore, under PCT Rule 13.2, the species lack the same or corresponding technical feature.

Applicant is required to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 11 are generic.

6. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a

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claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARA E. CLARK whose telephone number is (571) 270-7672. The examiner can normally be reached on Mon- Thu, 8:00 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Nolan, can be reached at 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sec

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121